

Geron trial -- baby steps toward a cure

Posted: October 11, 2010

Created: 11/10/2010 - 14:53

Today Geron announced that the first patient had been treated in their groundbreaking trial based on human embryonic stem cells.

At first blush: Woo hoo!! This is the first test of technology that holds hope for millions of people living with spinal cord injury and other diseases.

But it's important to remember that this first trial is a very, very early step. Any potential therapy goes through three rounds of human trials. The first, phase I, trial is intended only to verify that the potential therapy is safe. This trial can establish dosing and begin to monitor side effects of the drug or treatment. In some cases a phase I trial will also begin to reveal whether the drug or therapy has signs of effectiveness, but that's not the primary role of the trial.

After the small phase I trial comes a slightly larger phase II trial. It confirms safety and also begins to look directly at whether the drug or therapy is effective.

It isn't until some years later that a large phase III trial confirms whether the drug or therapy is effective compared to standard therapy.

Many potential therapies fail after the phase I trial, even after years of positive results in animals. Humans aren't mice (or other laboratory animals) and scientists can't ever know what side effects will turn up in their human patients.

That's why it is important to temper that initial "woo hoo" with a bit of patience. This could be one of those trials that fails phase I. Or phase II. Or phase III. But as many years of biomedical research have shown, for every failed trial there are also a number of successful trials. Whatever the results of this first phase I trial, it's the beginning of a new era that will one day result in the first successful therapy based on human embryonic stem cells. That day will have scientists and patients alike whooping for joy.

Here's patient advocate Roman Reed talking about what a stem cell therapy for spinal cord injury means to him:

Tags: Geron, spinal cord injury

Source URL: <https://www.cirm.ca.gov/blog/10112010/geron-trial-baby-steps-toward-cure>